

K96 0448

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**Li Medical**

### 510(K) SUMMARY

Device Sponsor: Li Medical, 4 Armstrong Road, Shelton, CT 06484,  
203-944-2800

Contact: Rhodemann Li, Vice President  
Date: December 31, 1995

Classification Name: Staple, Fixation, Bone  
Common Name: Bone anchor  
Proprietary Name: LM Anchor or other proprietary name

Predicate Devices: Mitek Surgical Products Mini Anchor (K921873 and  
K930892)  
Li Medical Bone Anchor (K951233)

Device Description: Made from surgical grade stainless steel (316L), the  
LM Anchor is designed with a crown and a center pin  
through which suture is passed to provide a means for  
soft tissue to bone attachment.

Intended Use: Shoulder (bankart repair), Hand (ulnar or lateral  
collateral ligament reconstruction), Wrist  
(scapholunate ligament reconstruction), Foot (hallux  
valgus reconstruction), and Ankle (midfoot  
reconstructions)

Technical Comparison: The LM Anchor is similar to the Mitek Mini Anchor in  
its cylindrical shape, however, the bony purchase is  
accomplished by the LM Anchor through cantilevered  
beams versus nitinol arcs with the Mitek Mini Anchor.

Performance Data: Pre-clinical testing in cadaver specimen showed that  
the mean pullout strength of the LM Anchor was  
substantially equivalent to the mean pullout strength of  
the Mitek Mini Anchor.